

DOCKET NO.: UPAP-0345
PATENT APPLICATION

SERIAL NO.: 09/359,975
FILED: JULY 23, 1999

Declaration of David B. Weiner

Provided herewith is a Declaration of co-inventor David B. Weiner which was submitted in a file wrapper continuation application Serial No. 08/453,349 of parent application Serial No. 08/029,336 which issued as U.S. Patent No. 5,830,876. The data in the declaration describe experiments in which immunity was generated using methods and compositions according to the invention. In particular, the experiments described in paragraph 16 et seq. Describe data generated from in vivo administration of DNA in bupivacaine. Applicants request that this declaration be considered together with the other evidence of record and arguments set forth in preceding responses.

Rejection under 35 U.S.C. §112, first paragraph

Claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, and 115-147 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in such a way as to enable one skilled in the art to make and use the invention.

The Examiner urges that the state of the art is such that one skilled in the art would require undue experimentation to practice the claimed invention. In particular, the Examiner urges that the field of DNA vaccines is unpredictable. The examiner cites references to support this argument. Applicants have urged the reports cited by the Examiner have been mischaracterized and repeat the assertion. Applicant urge that while it is true that the field of DNA vaccines will continue to be perfected as more is learned about the operation of the immune system and other biological systems related to the present invention, the invention is

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nonetheless sufficiently described to allow those skilled in the art to practice the invention without undue experimentation. There is no requirement for complete understanding of a scientific field of endeavor in order to provide enablement. Likewise, that an invention can be improved does not establish non-enablement. The present invention as set forth in the claims can be practiced by those skilled in the art. The evidence of record demonstrate this without question. That underlying scientific bases remain not fully understood and further advances can be made to improve design and application of the technology does not diminish its usefulness and enablement under the patent law.

Applicants respectfully urge that claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-157 are in compliance with the requirements of 35 U.S.C. §112. Applicants respectfully request that the rejections of claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-147 under 35 U.S.C. §112, first paragraph, be withdrawn.

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Conclusion

Applicants respectfully request that claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, and 115-157 be allowed. A Notice of Allowance is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully Submitted,



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Date: 2/28/02

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Enclosed: Declaration of David B. Weiner from Serial No. 08/453,349, U.S. Patent No. 5,830,876

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 148-157 have been added